

ASSEMBLY BILL

No. 1175

Introduced by Assembly Member Niello

February 23, 2007

An act to amend Section 1209.5 of the Business and Professions Code, relating to clinical laboratories, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1175, as introduced, Niello. Clinical laboratories: test results.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Services until June 30, 2007, and thereafter by the State Department of Public Health. Existing law makes a violation of these provisions a crime.

Existing law requires a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and document explicit criteria by which clinical laboratory test or examination results are autoverified, as defined.

This bill would instead require the laboratory director to ensure that laboratory test or examination results are not reported by the clinical laboratory until the results have been critically reviewed and verified, as specified, either by a person authorized to perform those tests or examinations or by autoverification, as specified.

Because the bill would revise requirements pertaining to clinical laboratories, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1209.5 of the Business and Professions
2 Code is amended to read:

3 1209.5. (a) *As part of the overall operation and administration*
4 *of a clinical laboratory, the laboratory director shall ensure that*
5 *laboratory test or examination results are not reported by the*
6 *clinical laboratory until the results have been critically reviewed*
7 *and verified for accuracy, reliability, and validity either by a*
8 *person authorized to perform the test or examination pursuant to*
9 *Section 1206.5 or by autoverification as specified in subdivision*
10 *(b).*

11 (b) (1) "Autoverification" means the use of a computer
12 algorithm in conjunction with automated clinical laboratory
13 instrumentation to review and verify the results of a clinical
14 laboratory test or examination for accuracy and reliability.

15 ~~(b)~~

16 (2) The laboratory director or authorized designee shall establish,
17 validate, and document explicit criteria by which the clinical
18 laboratory test or examination results are autoverified.

19 ~~(c)~~

20 (3) The laboratory director or authorized designee shall annually
21 revalidate the explicit criteria by which the clinical laboratory test
22 or examination results are autoverified. The laboratory director
23 shall approve and annually reapprove the computer algorithm.

24 ~~(d)~~

25 (4) An authorized designee ~~shall~~ *may* be appointed by the
26 laboratory director for the purposes of this ~~section~~ *subdivision*.
27 The authorized designee shall be licensed to engage in clinical
28 laboratory practice pursuant to this chapter and shall be qualified

1 as a clinical consultant, technical supervisor, general supervisor,
2 or technical consultant pursuant to regulations adopted by the
3 department.

4 (e)

5 (5) A person licensed to perform the applicable type and
6 complexity of testing pursuant to Section 1206.5 shall be physically
7 present onsite in the clinical laboratory and shall have documented
8 competency pursuant to Section 1209 in all tests being autoverified,
9 and shall be responsible for the accuracy and reliability of the
10 results of the clinical laboratory test or examination when the
11 results are autoverified and reported.

12 SEC. 2. No reimbursement is required by this act pursuant to
13 Section 6 of Article XIII B of the California Constitution because
14 the only costs that may be incurred by a local agency or school
15 district will be incurred because this act creates a new crime or
16 infraction, eliminates a crime or infraction, or changes the penalty
17 for a crime or infraction, within the meaning of Section 17556 of
18 the Government Code, or changes the definition of a crime within
19 the meaning of Section 6 of Article XIII B of the California
20 Constitution.

21 SEC. 3. This act is an urgency statute necessary for the
22 immediate preservation of the public peace, health, or safety within
23 the meaning of Article IV of the Constitution and shall go into
24 immediate effect. The facts constituting the necessity are:

25 In order to protect the public's health and safety as soon as
26 possible by clarifying the duties and responsibilities of clinical
27 laboratory personnel, it is necessary that this act take effect
28 immediately.